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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,504

05/06/2004

Rafail Zubok

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

08/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,504

Applicant(s)

ZUBOK ET AL.

Examiner

Ann Schillinger

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3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 13-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 13-15, 17, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Barber (US Pat. No. 5,236,460). Barber discloses the following of claim 1: an insertion plate, comprising: a base (13, 23); a first mounting element (upper 45) of the base operable to engage a first member (29) of an intervertebral disc replacement device; a second mounting element (lower 45) of the base operable to engage a second member (19) of the intervertebral disc replacement device, wherein the first and second mounting elements cooperate to engage and orient the first and second members of the intervertebral disc replacement device for simultaneous insertion into an intervertebral disc space of a spinal column (see Figure 3); and a stem (55) extending away from an anteriorly directed surface of the base and operable to facilitate movement of the intervertebral disc replacement device and insertion thereof into the intervertebral disc space such that the first and second members may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (col. 3, line 7-15), the stem being sized and shaped for engagement with an insertion handle (61) to further facilitate movement of the intervertebral disc replacement device, wherein one of the stem and the insertion handle includes

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a bore and the other of the stem and the insertion handle includes a tapered shaft that frictionally engages the bore to facilitate detachable engagement with one another (see Figure 5).

Barber discloses the limitations of claims 2 and 14 as shown in Figure 3.

Barber discloses the limitations of claims 3, 4, and 7 where the flange is element 47, the mounting hole is element 48, and the fastener/screw is element 53.

Barber discloses the limitations of claim 5 where the ledge member is element 39.

Barber discloses the following of claim 6: the insertion plate of claim 5, wherein the ledge member includes first (outer edges) and second (bottom, middle portion) spaced apart surfaces, at least one of the first and second spaced apart surfaces of the ledge member being contoured for engagement with respective surfaces of the first and second members of the intervertebral disc replacement device (engages with elements 13, 23) the first surface of the ledge member being curved and the second surface of the ledge member being flat (see Figure 8).

Barber discloses the following of claim 13: the insertion plate of claim 1, wherein the base is operable to detachably engage a flange of the first member of the intervertebral disc replacement device, and to detachably engage (see Figure 4) a flange of the second member of the intervertebral disc replacement device, wherein the first (upper 47) and second (lower 47) flanges include one or more respective through holes (48) for receiving bone screws (53) for fastening the first and second members to respective adjacent vertebral bones of the intervertebral disc space of the spinal column, and the base cooperates to orient the through holes of the first and second flanges of the intervertebral disc replacement device to have a

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configuration substantially similar to that of a spinal fusion plate when viewed from an anterior vantage point (see Figure 3).

Barber discloses the following of claim 15: an apparatus for replacing at least a portion of an intervertebral disc in a spinal column, comprising: first (133) and second (137) members of an intervertebral disc replacement device; and an insertion plate (11) detachably coupled to each of the first and second members of the intervertebral disc replacement device and operable to orient them for simultaneous insertion into an intervertebral disc space of the spinal column defined by respective endplates of adjacent vertebral bones, the insertion plate including: a base (13, 23); a first mounting element (upper 45) of the base operable to engage a first member (29) of an intervertebral disc replacement device; a second mounting element (lower 45) of the base operable to engage a second member (19) of the intervertebral disc replacement device, wherein the first and second mounting elements cooperate to engage and orient the first and second members of the intervertebral disc replacement device for simultaneous insertion into an intervertebral disc space of a spinal column (see Figure 3); and a stem (55) extending away from an anteriorly directed surface of the base and operable to facilitate movement of the intervertebral disc replacement device and insertion thereof into the intervertebral disc space such that the first and second members may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (col. 3, lines 7-15), the stem being sized and shaped for engagement with an insertion handle (61) to further facilitate movement of the intervertebral disc replacement device, wherein one of the stem and the insertion handle includes a bore and the other of the stem and the

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insertion handle includes a tapered shaft that frictionally engages the bore to facilitate detachable engagement with one another (see Figure 5).

Barber discloses the following of claim 17: a method for replacing at least a portion of an intervertebral disc in a spinal column, comprising the steps of: removing the portion of the intervertebral disc from the spinal column (col. 3, lines 7-9); detachably coupling first (13) and second (23) members of an intervertebral disc replacement device to an insertion plate (55) that is operable to orient the first and second members with respect to one another (see Figure 3); detachably coupling the insertion plate to a handle (61), wherein the insertion plate includes a stem (59) sized and shaped for engagement with the insertion handle and one of the stem and the insertion handle includes a bore and the other of the stem and the insertion handle includes a tapered shaft that frictionally engages the bore to facilitate detachable engagement with one another (see Figure 5); and simultaneously inserting the first and second members of into an intervertebral disc space of the spinal column by manipulating the handle and insertion plate (col. 3, lines 10-15), the first and second members being engageable with and operable to permit adjacent vertebral bones defining the intervertebral disc space to articulate with respect to one another (col. 2, lines 46-57).

Barber discloses the limitations of claims 19 and 20 in col. 3, lines 30-31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez Jimenez in view of Sanderson (U.S. Pat. No. 4,105,407). Ramirez Jimenez does not disclose the implant as being in a sterile package. Sanderson teaches this in col. 2, lines 54-56. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to make the implant part of a sterile assembly package to prevent infection and safeguard the patient.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 13-17, 19, and 20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
July 30, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER